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10/024,036	12/17/2001	Rajasekhar Bandaru	MPI00-5211PIRM	5438

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EXAMINER

STEADMAN, DAVID J

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 05/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/024,036

Applicant(s)

BANDARU, RAJASEKHAR

Examiner

David J. Steadman

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Status of the Application***

- [1] Claims 1-22 are pending in the application.
- [2] Applicant's amendment to the specification in the preliminary amendment of Paper No. 5, filed July 5, 2002, is acknowledged.

***Election/Restrictions***

- [3] Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claim(s) 1-7, 12, and 18, drawn to an isolated nucleic acid encoding SEQ ID NO:2 including SEQ ID NO:1 and 3, a host cell, a method for producing a polypeptide, and a kit comprising a compound that selectively hybridizes to a nucleic acid, classified in class 536, subclass 23.2.
  - II. Claim(s) 1-7, 12, and 18, drawn to an isolated nucleic acid encoding SEQ ID NO:5 including SEQ ID NO:4 and 6, a host cell, a method for producing a polypeptide, and a kit comprising a compound that selectively hybridizes to a nucleic acid, classified in class 536, subclass 23.2.
  - III. Claim(s) 8-10, drawn to the isolated polypeptide of SEQ ID NO:2, classified in class 435, subclass 194.
  - IV. Claim(s) 8-10, drawn to the isolated polypeptide of SEQ ID NO:5, classified in class 435, subclass 194.
  - V. Claim(s) 11 and 15, drawn to an antibody and kit comprising a compound that binds to the polypeptide of SEQ ID NO:2, classified in class 530, subclass 387.9.
  - VI. Claim(s) 11 and 15, drawn to an antibody and kit comprising a compound that binds to the polypeptide of SEQ ID NO:5, classified in class 530, subclass 387.9.
  - VII. Claim(s) 13 and 14, drawn to a method for detecting the presence of the polypeptide of SEQ ID NO:2, classified in class 435, subclass 15.

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- VIII.** Claim(s) 13 and 14, drawn to a method for detecting the presence of the polypeptide of SEQ ID NO:5, classified in class 435, subclass 15.
- IX.** Claim(s) 16 and 17, drawn to a method for detecting the presence of a nucleic acid encoding SEQ ID NO:2 including SEQ ID NO:1 and 3, classified in class 435, subclass 6.
- X.** Claim(s) 16 and 17, drawn to a method for detecting the presence of a nucleic acid encoding SEQ ID NO:5 including SEQ ID NO:4 and 6, classified in class 435, subclass 6.
- XI.** Claim(s) 19, 20, and 22, drawn to a method for identifying a compound that binds to or modulates the activity of the polypeptide of SEQ ID NO:2, classified in class 435, subclass 15.
- XII.** Claim(s) 19, 20, and 22, drawn to a method for identifying a compound that binds to or modulates the activity of the polypeptide of SEQ ID NO:5, classified in class 435, subclass 15.
- XIII.** Claim(s) 21, drawn to a method for modulating the activity of the polypeptide of SEQ ID NO:2, classified in class 435, subclass 194.
- XIV.** Claim(s) 21, drawn to a method for modulating the activity of the polypeptide of SEQ ID NO:5, classified in class 435, subclass 194.

**[4]** The inventions are distinct, each from the other because:

**[5]** The nucleic acids of Groups I and II are structurally distinct molecules that encode structurally distinct polypeptides and no single nucleic acid of Group I or II would render the other obvious to one of ordinary skill in the art.

**[6]** The polypeptides of Groups III and IV are structurally distinct molecules that elicit different antibodies and no single polypeptide of Group III or IV would render the other obvious to one of ordinary skill in the art.

**[7]** The antibodies of Groups V and VI were elicited by structurally distinct polypeptides and bind structurally distinct polypeptides and no single antibody of Group V or VI would render the other obvious to one of ordinary skill in the art.

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**[8]** The nucleic acids of Groups I and II, the polypeptides of Group III and IV, and the antibodies of Groups V and VI each comprises a chemically unrelated structure capable of separate manufacture, use, and effect. The nucleic acids of Groups I and II have other utility besides encoding polypeptides such as a hybridization probe, the polypeptides of Groups III and IV can be made by another method such as purification from the natural source or chemical synthesis, and the antibodies of Groups V and VI can be made using a polypeptide other than the polypeptides of Groups III and IV, such as a polypeptide purified from the natural source or synthetically produced.

**[9]** The polynucleotides of Group I and II are unrelated to the method(s) of Groups VII and VIII as they are neither used nor made by the method(s) of Groups VII and VIII.

**[10]** The polynucleotides of Groups I and II are related to the methods of Groups IX-XIV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Groups I and II can be used for protein expression of the polypeptides of Groups III and IV.

**[11]** The polypeptides of Group III and IV is related to the methods of Groups VII, VIII, and XI-XIV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Groups III and IV can be used in the production of the antibodies of Groups V and VI.

**[12]** The polypeptides of Groups III and IV are unrelated to the method(s) of Group IX and X as they are neither used nor made by the method(s) of IX and X.

**[13]** The antibodies of Groups V and VI are related to the methods of Groups VII and VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

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different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group III can be used as an affinity reagent for the purification of the polypeptides of Groups III and IV.

**[14]** The antibodies of Groups V and VI are unrelated to the method(s) of Groups IX-XIV as they are neither used nor made by the method(s) of Groups IX-XIV.

**[15]** The methods of Groups VII-XIV are independent as they comprise different steps, utilize different products and/or yield different results.


**[16]** MPEP § 803 sets forth two criteria for restricting between patentably distinct inventions – 1) the inventions must be independent or distinct and 2) there must be a serious burden on the examiner. MPEP § 803 states, "For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02". Because the inventions of Groups I-XIV are distinct for the reasons given above, have separate classification, and/or each of the inventions requires a separate patent and non-patent literature and/or sequence search, restriction for examination purposes is proper.

**[17]** Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

**[18]** It is noted that claims 1-22 will be examined only to the extent the claims read on the elected subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.  
Patent Examiner  
Art Unit 1652

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